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Original article

Informed consent for total hip arthroplasty: does a written information sheet improve recall by patients?

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***Objective*: To ascertain whether a written information sheet is acceptable to patients and improves recall of the consent interview.**
***Design*: Prospective randomised controlled study using questionnaires, comparing a group of patients given information in a written sheet with appropriate explanation to a group given verbal information alone.**
***Setting*: A specialist orthopaedic surgery unit.**
***Patients*: The test group was 126 patients undergoing revision or primary total hip arthroplasty; 65 patients were given information verbally, 61 patients were given written information.**
***Outcome measure*: Patients' recall of information given, tested with a questionnaire completed on admission (mean of 18 days later).**
***Results*: The patients receiving written information scored significantly higher (48% correct answers) than the patients receiving verbal information (38% correct answers).**
***Conclusions*: Written information sheets contribute to the process of informed consent. As patients' recall of information is generally poor, the sheets may also be useful medicolegally, as a permanent record of what was discussed.**

Key words: Informed consent – Total hip arthroplasty – Written/verbal information – Recall – Questionnaire

As long ago as 1914, Cordoza stated that: 'every human being of adult years and sound mind has a right to determine what shall be done with his body, and a surgeon who performs an operation without the patient's consent commits an assault for which he is liable in damages'.[1]

Informed consent is a legal requirement before any surgical procedure. The General Medical Council (GMC) has issued guidelines concerning informed consent for practitioners.[2] These state that: 'the patient must be given sufficient information, in a way that they can understand, in order to enable them to exercise their right to make informed decisions about their care'.

Total hip arthroplasty, in common with many modern operations, is a complex procedure, with important but uncommon risks. There is a large amount of information for a patient to comprehend in order to make an informed decision, and this is difficult, particularly when the information is delivered purely orally. Total hip arthroplasty is now a commonly performed procedure. Many patients will know relatives or friends who have had a successful arthroplasty and may, therefore, discount the risks unless fully understood.

Previous studies have investigated the recall of information given to patients, and various means of improving recall, such as coaching,[3,4] structured interviews,[5] and written

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information sheets for minor surgery.[6-8] There has been a study of patients undergoing total hip arthroplasty using a 4-page information booklet.[9] However, this was not randomised, and the two groups did not receive equivalent information. To our knowledge, there have been no randomised prospective studies comparing written information to verbal information for complex procedures such as arthroplasty.

We also wished to ascertain acceptability of the sheet to patients, as some colleagues are concerned that discussion of risks in detail may cause anxiety. A study carried out on ear, nose and throat patients showed that anxiety levels were higher on admission if the patients had not had a consent interview, but there was no significant difference between groups given an informal interview, a structured interview, or a written sheet and interview.[5]

Patients and Methods

Trial design

The trial was designed as a prospective randomised controlled trial. Following a pilot study, a power analysis was carried out by the unit's statistician, and the appropriate study group size determined.

Subject selection

All patients were seen in a pre-admission clinic prior to total hip arthroplasty at the Avon Orthopaedic Centre. This is a regional orthopaedic unit within a teaching hospital. A total of 127 consecutive patients, able to give their own consent, were seen in this clinic between September 1998 and July 1999 and then subsequently admitted for operation. One patient, a recently retired surgeon, was excluded from the study, as it was felt that his knowledge was likely to skew the results. No patients declined to take part. Therefore, 126 patients were available for study. The age of the patient, and whether they were undergoing primary or revision hip arthroplasty was documented.

Assignment

Each patient was individually randomised by computer-generated random number to either a written information sheet with verbal explanation or a structured verbal discussion of exactly the same information. The consent interview, with or without the information sheet, was carried out by the first author or by the operating surgeon.

The information sheet

The information sheet comprised a page and a half of widely-spaced, typewritten A4 paper with a picture of a typical total hip replacement for illustration. Non-medical alternative terms were used throughout, and care was taken to ensure 'readability', by 'proof-reading' carried out by non-medical personnel.

The sheet gave information about the operation and hospital stay, basic types of implants, anaesthetic and risks. Risks were discussed in terms of percentages, and included infection, loosening, nerve injury, dislocation, thromboembolic disease, death, and leg length inequality.

The patients in the verbal information group generally expressed a wish to receive written information. However, care was taken to ensure that no patient in the verbal information group obtained a sheet from a patient in the other group, although it is accepted that they may have been able to find other written material on the subject once they left the pre-operative assessment clinic. They were informed that they would be allowed to read the sheet once the questionnaire had been completed, as we felt that this would make them less likely to 'cheat'.

Outcome measures

Each patient was given a questionnaire on admission to hospital to test recall of the information supplied on the sheet and verbally. This was carried out by the second author, who was unaware of the randomisation results during the administration of the questionnaire. After the questionnaire had been administered, the patients were asked about acceptability of the information sheet, and their preferences for written or verbal information. The second author had no responsibility for consent or the design of the information sheet, to reduce bias on acceptability scores. Time between consent and questionnaire was recorded.

The questionnaire had one question on usual post-operative stay and 10 questions on risks of postoperative complications. The questions were of a multiple choice design with three stratified possible responses for each.

Statistical analysis

Statistical analysis was carried out using the Student's *t*-test.

Results

The distribution of the two groups with regards to possible confounding factors shows no significant differences, and is shown in Table 1. In particular, there was no significant difference between the number of revisions in the two groups, although there were slightly more in the verbal information group.

There was no correlation between score and age.

The results of the two groups show a statistically significant improvement in recall scores for the group

Table 1 Demographics of the two groups

	Verbal information	Written information
Number of patients	65	61
Age (years)	68	68
Primary arthroplasties	57	55
Revision arthroplasties	8	6
Time from consent to questionnaire (days)	18	17

given written information; these data are shown in Table 2, with examples of results for individual questions.

As expected, the patients undergoing revision hip arthroplasty recalled significantly more information than those undergoing primary arthroplasty (Table 3). However, this difference was mainly accounted for by the superior recall of patients for revision arthroplasty who received written information, compared with those given verbal information.

The patients responded to the information sheets favourably, and the sheets were certainly coveted by those patients in the verbal information group. Patient preferences are shown in Table 4.

Discussion

The difference between the two groups is statistically significant; however, recall is poor in both groups. The results are similar those found in other studies performed in a wide variety of specialities.[3–7] Recall has also been found to be affected by other factors, such as age.[10] Interestingly, that study showed that impaired cognitive function only reduced recall during in-patient stay.

Recall versus comprehension

Recall of information partially depends upon, but is not equivalent to, comprehension of information. Comprehension is necessary for the process of informed consent, whilst recall is not; however, recall is important for medicolegal purposes. Recall was assessed in this study, pure comprehension being virtually impossible to measure objectively in patients. This assessment was, therefore, necessarily quantitative rather than qualitative. All patients stated that they understood the information given during the consent interview before signing the consent form.

Although there are a minority of patients who prefer to receive no information at all, this is unacceptable practice in the UK, as defined by the GMC.[2] Once this was explained to patients, they did agree to be informed. These patients scored badly on the questionnaires, although their numbers are small. The written information sheets make little difference under these circumstances, probably because they are not read properly.

Table 2 Results of the questionnaire

	Verbal info.	Written info	*P* value
Total questionnaire score	4.2 (38%)	5.25 (48%)	0.0044
Question on likely length of stay	83%	90%	ns
Question on risk of infection	28%	43%	0.08
Question on treatment of infection with revision	42%	44%	ns
Question on risk of dislocation	35%	41%	ns
Question on risk of loosening	45%	41%	ns
Question on risk of nerve injury	31%	39%	ns
Question on risk of deep vein thrombosis	11%	31%	0.01
Question on risk of fatal pulmonary embolism	20%	31%	ns

info. = information

Table 3 Data shown for primary and revision arthroplasty patients

	Revision arthroplasty	Primary arthroplasty	*P* value
Mean score	5.8 (53%)	4.5 (41%)	ns
Verbal information	4.15	4.25	ns
Written information	7.83	4.85	0.01
P value	0.006	ns	

Table 4 Preferences of patients regarding the written information sheet

	Verbal information	Written information
Would prefer written information	64	61
Would prefer no information	1	0
Would prefer only verbal information	0	0

The ethical and legal basis of informed consent

The legal concept of informed consent broadly stands on three principles.[11] The patient must: (i) be mentally competent to make the decision; (ii) have adequate information upon which to base their decision; and (iii) reach a decision voluntarily, without duress or undue influence from health professionals, family or friends.[12]

This paper is primarily concerned with the second of these three principles. In Britain, there is no case law setting out how much information should be given to patients as part of informed consent. Traditionally, British

courts have relied on the 'Bolam principle'.[13] This is the test adopted in the case of *Bolam v The Governors of Friern Hospital*, which states that: 'medical practitioners will not be found negligent if they have acted in accordance with a practice accepted as proper by a body of responsible and skilled medical opinion'. However, increasingly the 'Bolam principle' is being superseded in British courts by the 'patient need standard' from the US.[14,15] In Australia, the 'Bolam principle' has now been superseded by the judgement of *Rogers v Whittaker* in 1992, in which an ophthalmic surgeon was found negligent in not warning of a 1 in 14,000 risk of sympathetic ophthalmia.[16]

Consent is an ethical duty and the discussion improves the doctor–patient relationship, which is of vital importance. Also, the concept of informed consent is valid and real legally, as long as the patient is informed at that moment, no matter how much of the discussion they have forgotten postoperatively. However, the GMC does suggest that, if consent is obtained in a pre-operative assessment clinic, this should be re-confirmed at the time of admission, if significant time has elapsed; our results would support this. Of course, the process of informed consent as an ethical duty must be regarded as a process and not a one-off event.[17]

Patient preferences

The preference of patients is another reason to consider using written information. The sheets also promote a sense of openness and partnership, which is increasingly recognised as important.[18] Indeed, the *Final Report of the Bristol Royal Infirmary Enquiry* states that: 'the provision of adequate information is an essential prerequisite to the development of trust. It underpins the honesty between professional and patient.'[19] It recommends information be given in a variety of formats, including verbal and written. This information must be accurate, and the amount and depth of information should be tailored to the individual patient.[17]

Written information is also useful for house officers taking consent. They are often ignorant of the risks themselves.[20] The Clinical Negligence Scheme for Trusts (set up by the NHS Executive in 1995) recommends that: 'consent for elective procedures is obtained by a person capable of performing the procedure', and this is the practice of our unit. However, the GMC recognises that this is not always possible in some practices or branches of surgery, and advises that this task may be delegated to a junior member of staff who: 'has sufficient knowledge of the proposed investigation or treatment, and understands the risks involved'.[2] Information sheets would, therefore, be useful for the education of junior staff, with much to learn in a short space of time.

Medicolegal implications

In the event of a complication, claims may depend on a patient's account of what was discussed as part of informed consent. If this recall is incorrect, then the wrong judgement may be made. Judges have decided that this is such an important event for patients that their recall will be better than that of their surgeon. Robinson and Merav tested recall 4–6 months' postoperatively, and found that patients were: 'frequently in error but never in doubt'.[21] There was only 10% recall of potential complications. Interestingly, the most authoritative patients achieved the poorest scores. Of the 20 patients, 16 denied that major items were discussed at all. The difficulty that patients (or parents) have in recalling the information given in the consent interview was recognised in the Bristol Royal Infirmary enquiry, which recommended that a tape recording be made for future reference.[19]

Medicolegally, the information sheet would be useful as a permanent record of what was discussed, if signed by both parties, to document that the information had been read and understood. This should prevent disputes and claims due to poor recall of the consent procedure.

Each unit should base its own information sheets on its own practice and audited results, rather than on published literature, which may not reflect general orthopaedic practice.

It is difficult to decide how much information should be included on an information sheet. A risk of 1% has often been taken as the threshold, but this should probably be discussed and clarified at a higher level, possibly by the relevant specialist society. Once a consensus has been reached on what should be included on the information sheet, this would act as a 'Bolam principle' in its own right.

Conclusions

Written information sheets are a useful adjunct to the informed consent interview. Written information improves recall of information, and is favoured by patients.

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